REMARKS

Applicants respectfully request reconsideration of the present application.

1. Disposition of the Claims and Specification

Claims 3-7, 9, 11, 13, 15, and 29-32 are pending. Claims 3-5, 9, 11, 13, 15, and 29 are currently amended. Claims 31-32 are newly added. Claims 1-2, 10, 16-17, 19, 22, 25 and 28 are withdrawn. Claims 8, 12, 14, 18, 20-21, 23-24 and 26-27 are canceled. Claims 3-5, 9 and 11 are amended to revise claim dependencies and to remove non-elected subject matter.

Support for the amendment to claim 3 may be found in the specification, for example, at page 13, lines 34-36. Support for the amendment to claims 13 and 31 may be found in the specification, for example, at page 5, line 32 to page 6, line 10. Support for the amendment to claims 15 and 32 may be found in the specification, for example, at page 6, lines 11-20. Support for the amendment to claims 11 and 29 may be found in the specification, for example, at page 13, lines 34-36 and at page 22, lines 13-18. Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

2. Restriction Requirement

Applicant has withdrawn claims 1-2, 10, 16-17, 19, 22, 25 and 28. Applicant has also withdrawn the subject matter of claims 3-7, 9, 11, 13, 15 and 29-30 not limited to SEQ ID NOs: 12 and 26. Claims 3-7, 99, 11, 13, 15 and 29-30, limited to SEQ ID NOs: 12 and 26, remain pending.

3. Claim Rejections – 35 U.S.C. § 112, second paragraph

Claims 3-5, 9, 11 and 15 are rejected under 35 U.S.C. § 112, second paragraph. The examiner finds claims 3-5, 9 and 11 "confusing in that they are drawn to claims not elected for prosecution and/or sequences not elected for prosecution." Applicants have amended claims 3-5, 9 and 11 to revise claim dependencies and so that they are drawn to only SEQ ID NOs: 12 and 26. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

The examiner also rejects claim 15 under 35 U.S.C. § 112, second paragraph because it is not known whether the recitation of "optionally" is "meant to be a limitation on the claim or simply illustrative." Applicants respectfully disagree with the examiner. However, to expedite prosecution, Applicants have amended claim 15 and added new claim 32. Support for the amendment to claim 15 and new claim 32 may be found in the specification, for example, at page 6, lines 11-20. The present version of the claims avoids this issue. The rejection should be withdrawn.

4. Claim Rejections – 35 U.S.C. § 101

The examiner has rejected claims 3-7, 9, 11, 13, 15 and 29-30 under 35 U.S.C. § 101 for not being supported by either a specific and substantial asserted utility or a well established utility. Applicants respectfully request reconsideration and withdrawal of the rejection.

According to the results of the attached sequence alignment, performed with SEQ ID NO: 12 of the instant invention, the protein identified in the specification having an amino acid sequence corresponding to SEQ ID NO: 12 is 99% identical to C20orf13. *See* Alignment (Exhibit 1). The annotation of C20orf13 (Exhibit 1) and associated post-filing PubMed article by Hsieh *et al.*, CELL 115(3):248-250 (2003) (Exhibit 1), show that C20orf13 is a threonine aspartase, termed Taspase1.

Hsieh *et al.* explains that a mutation in the Mixed-Lineage Leukemia gene (MML) is responsible for a certain type of human infant leukemia. *See* Hsieh *et al.*, p. 293. According to Hsieh *et al.*, the MLL gene is cleaved and processed by the Taspase1 protease, which confers the correct nuclear sublocalization on the MLL gene product, allowing for expression of the HOX gene which in turn causes the infant to develop leukemia. *See* Hsieh *et al.*, p. 293, 298. The authors have also demonstrated that knockdown of Taspase1 prevents MLL cleavage and decreases HOX gene expression. *See* Hsieh *et al.*, p. 298, 300. Finally, the authors explain that such a protease can be used to develop "targeted therapeutics" for diseases involving specific pathways, such as that described above for MLL. *See* Hsieh *et al.*, p. 293. The protease may also be used to develop an inhibitor that could impair HOX expression for the treatment of leukemia. *See* Hsieh *et al.*, p. 301.

Similarly, the present specification discloses the use of the claimed polynucleotides and polypeptides in the treatment and prevention of various diseases, including leukemia, on page 36, line 28. As demonstrated by Hsieh *et al.*, the claimed protein is a threonine aspartase that is involved in MML cleavage, HOX gene expression, and the development of a particular infant leukemia. Therefore, the claimed invention may be used in the treatment and prevention of the MML-associated infant leukeumia. Accordingly, the claimed polynucleotides and polypeptides of the instant invention do have a specific and substantial asserted utility. Because the invention has at least one substantial and credible utility, the § 101 rejection is improper and should be withdrawn.

5. Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 3-7, 9, 11, 13, 15 and 29-30 are rejected under 35 U.S.C. § 112, first paragraph. The examiner reasons that because the claimed invention is not supported by a specific and substantial asserted utility, one skilled in the art would not know how to use the claimed invention. Applicants have established a specific and substantial asserted utility as described in section 4 above. The § 112, first paragraph, rejection is improper and should be withdrawn.

The examiner has further rejected claims 11, 13, 15 and 29-30 under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. First, with respect to the claims drawn to a polynucleotide 70% identical to SEQ ID NO: 26, the examiner reasons that "the specification contains no guidance as to what nucleotides can be changed, added or deleted to SEQ ID NO: 26 and still have the same properties of the sequence." Office Action at 6. Applicants respectfully disagree with the examiner and request reconsideration of this rejection.

In order to expedite prosecution, Applicants have amended claims 11 and 29 so that these claims are drawn to a polynucleotide 90% identical to SEQ ID NO: 26. Support for this amendment may be found in the specification at page 22, lines 13-18. Further, Applicants note that Table 2 of the instant specification discloses various portions of SEQ ID NO: 12, which is encoded by SEQ ID NO: 26, that are important to the disclosed function. Specifically, Table 2 discloses potential phosphorylation sites, potential glycosylation sites,

and signature sequences such as (1) ATP/GTP-binding site (P-loop); (2) Hydrolase N4 precursor; and (3) Hydrolase N4 precursor protein signal/1-asparaginase. Applicants assert that one of skill in the art would know to not modify the above-described portions of SEQ ID NO: 12 so that the polynucleotide variant that is 90% identical to SEQ ID NO: 26 would encode a protein that still retains the same properties of the polypeptide represented by SEQ ID NO: 12.

Second, with respect to claims drawn to at least 60 contiguous nucleotides of SEQ ID NO: 26, the examiner reasons that claim 29 "reads on polynucleotide molecules that consist of 60 nucleotides from anything whatsoever having 60 contiguous nucleotides." Applicants respectfully disagree with the examiner. However, to expedite prosecution, Applicants have amended claim 29. Support for the amendment to claim 29 may be found in the specification, for example, at page 13, lines 34-36 and at page 22, lines 13-18. The present version of the claim avoids this issue. The rejection should be withdrawn.

6. Claim Rejections – 35 U.S.C. § 102

Claim 3 is rejected under 35 U.S.C. § 102(b) as being anticipated by Evans, *et al.* According to the examiner, Evans, *et al.* "apparently teaches the genomic DNA encoding at least an immunogenic fragment of SEQ ID NO: 12." Office Action at 7. However, the examiner has not shown how Evans, *et al.* discloses any sequence that actually does encode a immunogenic fragment of SEQ ID NO: 12.

Because the examiner has not provided an alignment between SEQ ID NO: 12 and the genomic DNA sequence of Evans *et al.*, Applicants have made several attempts using different alignment programs (various BLAST programs, clustalW, and crossmatch) to create their own alignment between the amino acid sequence of SEQ ID NO: 12 and the amino acid sequence encoded by the nucleotide sequence identified in Evans, *et al.* Applicants have not been able to create any alignment between SEQ ID NO: 12 and the genomic DNA sequence of Evans, *et al* of more than 5-6 amino acids.

In order to expedite prosecution, Applicants have amended claim 3 to recite immunogenic fragments of at least 10 contiguous amino acids of SEQ ID NO: 12. Support for the amendment to claim 3 may be found in the specification, for example, at page 13, lines 34-36. Applicants respectfully request reconsideration and withdrawal of the rejection.

7. Claim Rejections – 35 U.S.C. § 103

Claims 3, 6-7 and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans, *et al.* The examiner reasons that it would have been obvious "to link a promoter to the polynucleotide, put this into a host cell and produce a polypeptide by using a host cell containing the polynucleotide." Office Action at 7.

Applicants respectfully disagree with the examiner and request reconsideration and withdrawal of the rejection. As explained above in section 6, Evans *et al.* does not actually teach the genomic DNA that encodes any of the claimed polypeptides of the instant invention. Therefore, without a polynucleotide sequence to start from, it would not have been obvious to create the claimed polypeptides, even if it one of ordinary skill in the art would have known to link a promoter to such a polynucleotide, and place this in a host cell in order to produce a polypeptide.

8. Conclusion

Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of

papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 8/26/04

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